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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,857	03/08/2005	Claudio Soto	2641-1-001PCT/US	3342

23565 7590 01/09/2008

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,857	SOTO ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-19* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed October 15, 2007 in response to the Office Action of June 11, 2007, is acknowledged and has been entered. Previously pending claims 12-19 have been amended. Claims 12-19 are currently pending and being examined.

Claim Objections

2. Claim 14 is objected to because of the following informalities: Claim 14 ends with two periods and should end in only one. Appropriate correction is required.

New Rejections

(necessitated by amendments)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the limitation "**the** apoptogenic-bacteriocin capable of inducing apoptosis". There is insufficient antecedent basis for this limitation in the claim.

4. Claims 12, 13, 15, 17, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "molecular weight less than **10,000**" without reciting a unit of measurement for the molecular weight. The weight of the protein is unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

The claims are drawn to methods for apoptosis of tumor or cancer cells, reducing or blocking eukaryotic cell growth, or treating cancer in a mammal comprising administering an apoptogenic-bacteriocin capable of inducing apoptosis in eukaryotic tumor cells or cancer cells, wherein the apoptogenic-bacteriocin is not toxic to normal eukaryotic cells, is a pore-forming or channel forming bacterial protein of molecular weight less than 10,000 and is microcin E492 **or an active fragment or analog thereof, said analog having mutations or alterations in the microcin E492 amino**

acid sequence, wherein said fragment or analog is capable of inducing apoptosis in eukaryotic cells, eukaryotic tumor cells or cancer cells, or comprising administering an apoptogenic-bacteriocin comprising the amino acid sequence of SEQ ID NO:2 **or an active fragment or analog thereof, said analog having mutations or alterations in SEQ ID NO:2, wherein said fragment or analog is capable of inducing apoptosis in eukaryotic cells, eukaryotic tumor cells or cancer cells**.

The specification discloses SEQ ID NO: 2 for the processed, active microcin E492 (p. 4, section 010; p. 10, section 030; Figure 7). The specification discloses that active microcin E492 (SEQ ID NO:2) was administered to HeLa cells *in vitro* and induced cell death via apoptosis (Example 6, p. 50). The specification does not disclose any other active fragments or analogs of microcin E492 having mutations or alterations in the microcin E492 amino acid sequence that are capable of inducing apoptosis in eukaryotic tumor cells or cancer cells, or active fragments or analogs of SEQ ID NO:2 having mutations or alterations in SEQ ID NO:2 and are capable of inducing apoptosis in eukaryotic tumor cells, as broadly encompassed in the claims.

The art (see Lagos et al, J of Bacteriology, 1999, 181:212-217; Figure 1) teaches the sequence of microcin E492 (see sequence search "20070524_13305_us-10-506-857-2.rup", Result # 1, UniProt database, from previous office Action), however the sequence of microcin E492 does not provide and adequate representative number of species to support adequate written description for the broad genus of active fragments or analogs of microcin E492 or SEQ ID NO:2 as encompassed by the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of "active fragment or analog thereof, said analog having mutations or alterations in the microcin E492 amino acid sequence, wherein said fragment or analog is capable of inducing apoptosis" in eukaryotic cells, eukaryotic tumor cells or cancer cells, or "an active fragment or analog thereof, said analog having mutations or alterations in SEQ ID NO:2, wherein said fragment or analog is capable of inducing apoptosis in" eukaryotic cells, eukaryotic tumor cells or cancer cells. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that " [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure,

formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted

the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of active fragments or analogs thereof, per Lilly by structurally describing representative active fragments or analogs for microcin E492 or SEQ ID NO:2 or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe active fragments or analogs thereof useful in the claimed invention in a manner that satisfies either the Lilly

or Enzo standards. Although the specification discloses SEQ ID NO:2 as the processed, active microcin E492 that is capable of inducing apoptosis in eukaryotic tumor or cancer cells, this does not provide a description of the broadly claimed active fragments or analogs thereof that would satisfy the standard set out in Enzo because the specification provides no structural features coupled to the claimed functional characteristics.

Further, the specification also fails to describe the active fragments or analogs thereof for microcin E492 or SEQ ID NO:2 by the test set out in Lilly because the specification describes only SEQ ID NO:2 for microcin E492 that is capable of inducing apoptosis in eukaryotic tumor or cancer cells. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of active fragments or analogs thereof having mutations or alterations in the microcin E492 amino acid sequence or SEQ ID NO:2, wherein said fragments or analogs are capable of inducing apoptosis in eukaryotic cells, eukaryotic tumor cells or cancer cells that is required to practice the claimed invention. Since the specification fails to adequately describe the product to which the claimed method uses, it also fails to adequately describe the method.

Relevant Arguments

6. Applicants argue that the specification and claims describe specific and particular characteristics and capabilities of the apoptogenic-bacteriocin, particularly E492,

suitable for and of use in the claimed methods. These provide tests for determining the capability and suitability of an active fragment or analog of microcin E492 or of SEQ ID NO:2 in the claimed methods. Applicants argue that it is well within the capability and knowledge of the skilled artisan to make and test any such active fragments or analogs for use in the claimed methods and it is therefor unnecessary to further detail fragments or analogs of the genus. Applicants argue the skilled artisan can readily do so, particularly given the teachings of the specification, his/her knowledge, and specific distinguishing and identifying characteristics of the genus as set out in the specification and in the claims (p. 7).

The arguments have been considered but are not found persuasive. The claimed active fragments and analogs encompass a broad genus of unknown sequences and does not define the structural features commonly possessed by members of the genus that can distinguish it from others. As stated in the above rejection: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Although the specification provides SEQ ID NO:2 for the microcin E492 apoptotic-bacteriocin that functions to induce apoptosis in eukaryotic tumor or cancer cells, the specification and claims do not identify which structural features are conserved among the fragments or analogs having any mutations or alteration in the microcin E492 amino acid sequence or in SEQ ID NO:2 that are capable of inducing apoptosis in eukaryotic cells, eukaryotic tumor cells or

cancer cells, or which structures constitute a substantial portion of the genus in order for one to visualize or recognize the identity of the members of the genus, hence the written description for the genus of fragments or analogs in the claimed methods do not meet the standards of Lilly.

Further, although the specification discloses SEQ ID NO:2, microcin E492, that functions in inducing apoptosis in eukaryotic tumor cells or cancer cells, neither the claims nor the specification teach the amino acids critical to the function, *i.e.*- inducing apoptosis in eukaryotic cells, eukaryotic tumor cells or cancer cells, of the broad genera of any fragment or analog of microcin E492 or SEQ ID NO:2. There are no specific structures, identifying characteristics, partial or complete structures, or known or disclosed structures coupled to the claimed functions for the broad genus of active fragments and analogs as recited in the claims, hence, the specification does not provide adequate written description according to the standards of Enzo.

The specification has not provided adequate written description for the broad genus of active fragments and analogs for the reasons above, hence one of skill in the art could not readily identify or distinguish which of the broadly claimed active fragments and analogs would function as claimed. Although Applicants suggest a skilled artisan can screen for the claimed active fragments and analogs, the court found in (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004) that screening assays, are not sufficient to enable an invention because they are merely a wish or plan for obtaining the claimed chemical invention.

Maintained Rejection

Claim Rejections - 35 USC § 112

NOTE: It is noted that the lack of enablement for apoptosis in ***any* cells undergoing any aberrant growth** in a mammal has been withdrawn in view of the amendments that deleted the limitation "cells undergoing any aberrant growth". It is noted claims 12, 13, 15, 17, and 18 were amended to change in scope to administering microcin E492 or active fragments or analogs thereof.

7. **Claims 12-16 and 19 remain rejected and claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph**, because the specification, while being enabling for **a method for apoptosis of tumor cell or cancer cells in a mammal, the treatment of cancer in a mammal, and reducing cancer growth in a mammal, comprising administering to said mammal an effective amount of the apoptogenic-bacteriocin microcin E492 or comprising SEQ ID NO:2**, does not reasonably provide enablement for a method for reducing *any eukaryotic cell growth* or *blocking eukaryotic growth*, comprising administering the said mammal an effective amount of the claimed apoptogenic-bacteriocins; and does not reasonably provide enablement for a method for apoptosis of tumor cell or cancer cells, reducing eukaryotic growth, or treating cancer in a mammal comprising administering any *active fragments or analogs of microcin E492 or SEQ ID NO:2*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

practice the invention commensurate in scope with these claims (see section 7 of previous Office Action).

The claims are drawn to methods for apoptosis of tumor or cancer cells, **reducing or blocking eukaryotic cell growth**, or treating cancer in a mammal comprising administering an apoptogenic-bacteriocin capable of inducing apoptosis in eukaryotic tumor cells or cancer cells, wherein the apoptogenic-bacteriocin is not toxic to normal eukaryotic cells, is a pore-forming or channel forming bacterial protein of molecular weight less than 10,000 and is microcin E492 or an active fragment or analog thereof, said analog having mutations or alterations in the microcin E492 amino acid sequence, wherein said fragment or analog is capable of inducing apoptosis in eukaryotic cells, eukaryotic tumor cells or cancer cells, or comprising administering an apoptogenic-bacteriocin comprising the amino acid sequence of SEQ ID NO:2 or an active fragment or analog thereof, said analog having mutations or alterations in SEQ ID NO:2, wherein said fragment or analog is capable of inducing apoptosis in eukaryotic cells, eukaryotic tumor cells or cancer cells.

The specification discloses that active microcin E492 (SEQ ID NO:2) was administered to HeLa cells *in vitro* and induced cell death via apoptosis (Example 6, p. 50). The specification discloses that microcin E492 functions as an apoptogenic-bacteriocin (p. 4, section 010).

The art teaches that microcin E492 is able to kill some human cell lines *in vitro* but not others. Hetz et al (PNAS, 2002, 99:2696-2701) teach that microcin E492 was administered to these cells *in vitro*: HeLa (an epithelial cell line derived from human

cervix carcinoma), KG-1 (monocyte-macrophage cell line), RJ2.25 (variant of the Raji B-LCL), Jurkat (a T-cell derived from acute T-cell leukemia), Ramos (a B-cell line originated from Burkitt's lymphoma, and AMG-3 (human endothelial cells from human tonsils) (p. 2697, col. 1). Non-cancerous cell lines KG-1 and AMG-3 were *insensitive* to microcin E492, all other cell lines were sensitive, at different degrees, to the microcin E492 toxic effect (p. 2698, col. 2; Table 1).

One cannot extrapolate the disclosure of the specification to the scope of the claims because the specification does not provide examples or guidance for **reducing *any* eukaryotic cell growth** in a mammal. The specification and the art (Hetz et al, above) teach a reduction in *cancerous* cell growth. Hetz et al teach that administration of microcin E492 *in vitro* did not affect the growth of two normal human cell lines that would be considered eukaryotic cells. Given the art teaches the *inability* of two bacteriocins to kill any and all types of eukaryotic cells, one of skill in the art could not predictably reduce any and all eukaryotic cell growth, unless cancerous, as broadly encompassed by the claims.

One cannot extrapolate the disclosure of the specification to the scope of the claims because the specification does not provide examples or guidance for **blocking eukaryotic cell growth in a mammal.** In the art, Farkas-Himsley et al II (1995, PNAS, 92:6996-7000) teach that the administration of an apoptogenic-bacteriocin VT1 *in vivo* wherein tumor growth was NOT blocked (see rejection in section 6 of previous Office Action with regards to "prevention" of cancer). Neither the specification nor the art teach

or enable the blocking of any eukaryotic cell growth comprising administering any apoptogenic-bacteriocin.

Finally, one cannot extrapolate the disclosure of the specification to the scope of the claims because the specification does not provide examples or guidance for apoptosis of tumor cells or cancer cells, treating cancer or reducing cancer growth comprising administering any **unknown active fragments or analogs** of microcin E492 or SEQ ID NO:2. Again, the specification has not disclosed the required or conserved structure of any active portions or analogs required to function for inducing apoptosis in eukaryotic cells, eukaryotic tumor cells or cancer cells. The specification and the art (Hetz et al above) teach the induction of apoptosis in cancerous cell lines comprising administering microcin E492 (SEQ ID NO:2), however, no active fragment or analog is disclosed that would predictably function to induce apoptosis in eukaryotic cells, eukaryotic tumor cells or cancer cells as claimed, hence one of skill in the art would not know how to make the claimed active fragment or analog that would predictably function as claimed.

Therefore, in view of the state of the art, the breadth of the claims, lack of guidance in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

Response to Arguments

8. Applicants state that the amended claims are more particularly directed to apoptosis of tumor or cancer cells. Applicants argue that the specification, particularly in

view of the significant skill of the skilled artisan, fully enables the making, testing and use of the claimed active fragments and analogs of microcin E492 and of SEQ ID NO:2. Applicants argue the specification and the claims set out and describe specific and particular characteristics and capabilities of the apoptogenic-bacteriocin, particularly E249 and/or SEQ ID NO:2 and active fragments or analogs thereof, suitable for and of use in the claimed methods. These provide tests for determining the capability and suitability of an active fragment or analog of microcin E492 or SEQ ID NO:2 in the claimed methods. It is well within the capability and knowledge of the skilled artisan to make and test any such active fragments or analogs for use in the claimed methods (p. 8).

The arguments have been considered but are not found persuasive. Although Applicants state that the amended claims are more particularly directed to apoptosis of tumor or cancer cells, this is not true of claims 15 and 16 which are drawn to methods of reducing or blocking euakryotic cell growth in a mammal, and are not drawn to apoptosis of tumor or cancer cells. Applicants did not address Examiner's arguments drawn to the lack of enablement for reducing any eukaryotic cell growth or blocking eukaryotic growth in section 7, pages 14-15 of the previous office Action.

With regards to the enablement of active fragments or analogs of microcin E492 or SEQ ID NO:2, the specification has not provided adequate written description for the broad genus of active fragments and analogs comprising unknown sequences for the reasons above, hence one of skill in the art would not know which of the broadly claimed fragments and analogs would predictably function as claimed, hence would not

know how to make and use the broadly claimed fragments and analogs. Although Applicants suggest a skilled artisan can screen for the claimed active fragments and analogs, the court found in (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004) that screening assays, are not sufficient to enable an invention because they are merely a wish or plan for obtaining the claimed chemical invention.

9. Applicants argue that the state of the art for monoclonal antibodies at the time of filing the invention was significant; the predictability is enhanced by the disclosure and identification of several exemplary antibodies, the amount of direction or guidance is appropriate, particularly given the significant skill and knowledge of the skilled artisan at the time; the claims set out the appropriate breadth by providing specific testable characteristics for the antibodies of use in the methods; and the quantity of experimentation, while significant, is not undue (p. 8-9).

The arguments have been considered but are not found persuasive because Applicants are arguing limitations not recited in the claims. There are no antibodies recited in the claimed methods.

10. All other rejections recited in the Office Action mailed June 11, 2007 are hereby withdrawn.

11. **Conclusion:** No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER